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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,948

Applicant(s)

HANASH ET AL.

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 6-13 and 19-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response filed November 10, 2004 is acknowledged and has been entered.
2. Claims 1-32 are pending in the application. Claims 6-13 and 19-32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention or species of invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in paper filed January 21, 2003 (Paper No. 7).
3. Claims 1-5 and 14-18 are currently subject to examination.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Grounds of Rejection Maintained

Claim Rejections - 35 USC § 112

5. The rejection of claim 14 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This ground of rejection is set forth in section 6 of the previous Office action mailed May 11, 2004.

At pages 6 and 7 of the amendment filed November 10, 2004, Applicant has traversed this ground of rejection, arguing that the specification contemplates the use of a genus of components that may be useful in detecting S100 proteins, including polypeptides, other than antibodies, that bind specifically to S100 proteins.

Applicant's argument has been carefully considered but not found persuasive for the reasons set forth in the previous Office action. In particular, a generic statement

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that defines a genus of such components by only their functional activity does not provide an adequate written description of the genus. Moreover, because there is no particularly identifying structural feature that is shared by the otherwise structurally and functionally different members of the genus of components useful in detecting S100 proteins that correlates with their common utility, one skilled in the art could not immediately envision, recognize, or distinguish at least a substantial number of the members of the claimed genus. Given that the members of the genus vary markedly in both structure and function, an adequate written description of the genus requires more than the mere description of a single species, such as an antibody that bind S100 proteins, because antibodies are not representative of at least most of the members of the genus of components useful in detecting S100 proteins. Finally, apart from an antibody that binds S100 proteins, the specification has not described any other members of the genus by, for example, reciting their detailed structures, formulas, chemical names, or physical properties. Therefore the disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, "Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 2, 4, 5, 14, and 15 under 35 U.S.C. 102(a) as being anticipated by WO 98/35985 A1 is maintained.

This ground of rejection is set forth in section 8 of the previous Office action mailed May 11, 2004.

At pages 7 and 8 of the amendment filed November 10, 2004, Applicant has traversed this ground of rejection, arguing that the primary focus of the cited reference is a detection method based on tumor tissue.

Applicant's argument has been carefully considered but not found persuasive, since the reference teaches that which is set forth in the previous Office action and the all of the limitations of the claims are met by those teachings.

7. The rejection of claim 14 under 35 U.S.C. 102(b) as being anticipated by BIO-RAD Life Sciences Research Products Price List Q (March 1991) is maintained.

This ground of rejection is set forth in section 9 of the previous Office action mailed May 11, 2004.

At page 8 of the amendment filed November 10, 2004, Applicant has traversed this ground of rejection, arguing that the reference merely teaches kits that may be used for immunoprecipitation, Western blotting, cell labeling, flow cytometry, etc., without teachings the specific detection of S100 proteins.

Applicant's argument has been carefully considered but not found persuasive, since the claim is drawn to a kit comprising a component for detecting the presence of S100 protein in a biological sample. The claim has been given its broadest, reasonable interpretation that is consistent with the supporting disclosure and consistent with the interpretation that the skilled artisan would reach. The component of the kit is not structurally or functionally limited by the claim. The reference teaches a kit comprising one or more components useful for detecting S100 proteins; therefore, all the limitations of the claim are met by that teaching.

8. The rejection of claims 14 and 15 under 35 U.S.C. 102(a) as being anticipated by Newton et al. (*J. Immunol.* **160**: 1427-1435, 1998) is maintained.

This ground of rejection is set forth in section 10 of the previous Office action mailed May 11, 2004.

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At pages 8 and 9 of the amendment filed November 10, 2004, Applicant has traversed this ground of rejection, arguing that Newton et al. fails to disclose a kit for diagnosis of cancer.

Applicant's argument has been carefully considered but not found persuasive, because the intended use recited in the preamble of claim does not structurally limit the kit, which comprises an anti-S100 antibody. The patentability of the claim is determined by structure of the kit and its components only. The prior art teaches an anti-S100 antibody, which is commercially available and pre-packaged. Absent a showing of any difference, the product disclosed by the prior art is deemed the same as the claimed invention.

Claim Rejections - 35 USC § 103

9. The rejection of claim 3 and 16-18 under 35 U.S.C. 103(a) as being unpatentable over WO 98/35985 A1, as applied to the rejection of claims 1, 2, 4, 5, 14, and 15 set forth *supra*, in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991; pages 190 and 233-240) is maintained.

This ground of rejection is set forth in section 12 of the previous Office action mailed May 11, 2004.

At pages 9 and 10 of the amendment filed November 10, 2004, Applicant has traversed this ground of rejection, arguing that the claimed invention would not have been obvious because the primary reference discloses a method based primarily on tumor tissue and there was no motivation to combine the references.

Applicant's argument has been carefully considered but not found persuasive for the following reasons:

In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Furthermore, the primary reference teaches that which is set forth in section 8 of the previous Office action; and is therefore anticipatory of the inventions of claims 3 and 16-18.

However, the primary reference does not teach an immunoprecipitation assay is used to detect S100 protein; nor does the primary reference teach a kit comprising a detectably labeled anti-S100 antibody, or an anti-S100 antibody and a detectably labeled secondary antibody that binds to the anti-S100 antibody.

The secondary reference teaches or suggests the deficiencies of the primary reference, such that the invention would have been obvious to one ordinarily skilled in the art at the time of the invention.

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as suggested by the secondary reference, it was routine and conventional at the time of the invention to detect and/or quantify a protein by immunoprecipitation. Moreover, it was routine and conventional to detectably label the antibody used to immunoprecipitate a protein to which the antibody binds in the process of detecting and/or quantifying the protein by immunoprecipitation and other immunoassays; and it was routine and convention to use a labeled secondary antibody that binds the antibody used to immunoprecipitate a protein in the process of detecting and/or quantifying the protein by a process comprising immunoprecipitation and other immunoassays, e.g., Western blot analysis. One ordinarily skilled in the art would have been motivated therefore to combine the references to derive the claimed invention for use in detecting S100 proteins, and the primary reference teaches detecting and/or quantifying MRP14/S100-A9 in the serum of a subject provides an indication of the presence of a lung tumor in the subject. Furthermore, it was routine and conventional at the time of invention to manufacture

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and use kits comprising reagents used in the same process, including such processes for detecting proteins. One of ordinary skill in the art at the time of invention would have been motivated to do so because kits provide ease and convenience.

Double Patenting

10. The provisional rejection of claims 1, 2, 4, and 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424 is maintained.

This ground of rejection is set forth in section 14 of the previous Office action mailed May 11, 2004.

At page 11 of the amendment filed November 10, 2004, Applicant has stated a terminal disclaimer will be filed upon notification of allowable claims.

11. The provisional rejection of claims 3 and 14-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of copending Application No. 10/461,424, as applied to claims 1, 2, 4, and 5 in the obviousness-type double patenting rejection above, and further in view of BIO-RAD Life Sciences Research Products Price List Q (March 1991; pages 190 and 233-240) is maintained.

This ground of rejection is set forth in section 15 of the previous Office action mailed May 11, 2004.

At page 11 of the amendment filed November 10, 2004, Applicant has stated a terminal disclaimer will be filed upon notification of allowable claims.

Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 4, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
2/7/05